AMENDMENTS TO THE DRAWINGS

The attached sheets of drawings include changes to FIGS. 1, 2 and 4. New FIG. 14 has been added. The Replacement Sheet demarcated as 1/7, which includes FIGS. 1 and 2, replaces the original sheet 1/7, which included FIGS. 1 and 2. The only difference between the Replacement Sheet 1/7 and the original sheet 1/7 is that the Replacement Sheet has been amended to indicate that FIGS. 1 and 2 are prior art.

The Replacement Sheet demarcated as 2/7, which includes FIGS. 3 and 4, replaces the original sheet 2/7, which included FIGS. 3 and 4. FIG. 3 has not been amended. With reference to FIG. 4, the previously described but omitted spacer is now indicated as element 60. Support for this amendment may be found at paragraph [0068], page 22.

The Replacement Sheet demarcated as 7/7, which includes FIGS. 13a - c and 14, replaces the original sheet 7/7, which included FIGS. 13a-c. FIGS. 13a-c have not been amended. FIG. 14 has been added to show the previously described but omitted membrane, which is indicated as element 53, with radial scoring, which is indicated as element 70. Support for this amendment may be found at paragraph [0050], page 25 and paragraph [0086], page 28.

REMARKS

FORMAL MATTERS:

Claims 1-41 and 55 are pending after entry of the amendments set forth herein.

Claims 42-54 and 56-63 were previously canceled without prejudice.

Claims 8, 35, and 38-41 are withdrawn from consideration.

Claims 24, 25 and 30 are amended. Support for these amendments is found throughout the specification and in the claims as originally filed. For instance, support may be found in Figure 5, element 57, as well as at paragraph [0053], beginning on page 16 and continuing to page 17. Accordingly, no new matter has been added.

OBJECTIONS TO THE CLAIMS

Claim 30 has been objected to for allegedly containing a typographical error. Accordingly, claim 30 has been amended. In view of the amendment to claim 30, this objection has been obviated and the Applicants respectfully request its withdrawal.

REJECTIONS UNDER §112, ¶1

Claims 10, 12, 18, 30, 31 and 32 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement.

The Office Action asserts that claims 12, 31 and 32 recite a nozzle that is contoured so as to cause "no oblique shock waves are formed in said substantially quasi-steady flow" and to cause "any expansion downstream of the duct section to provide generally radially uniform particle distribution at the exit of the divergent portion and generally radially uniform particle distribution, with a substantially parallel velocity of particles and gas exiting the device." The Office Action acknowledges that the specification states that a contoured or simple correctly expanded nozzle achieves no oblique shocks and uniform flow. The Office Action, however, asserts that there is no description as to what is regarded as a contoured nozzle and because of this lack of description one of skill in the art would not be able to make the claimed invention.

The Applicants respectfully disagree and contend that the design and making of a contoured nozzle is well known and commonly practiced within the art. To support this contention the Applicants would like to draw the attention of the Office to the included reference entitled *Modern Compressible*

Flow by John D. Anderson Jr., which was published in 1990. The Anderson reference is a standard textbook which outlines various well known concepts of nozzle design. Chapter 5.4 of the Anderson reference discloses design considerations of various nozzles. Specifically, page 163 discusses the design of contour nozzles. Additionally, Figure 5.12 (b), on page 161, shows a supersonic isentropic solution which shows the variation of Mach number over the length of the nozzle. The dotted line shows the solution where no normal shockwaves are in the nozzle. Furthermore, Chapter 11 explains how the nozzle may be contoured. Specifically, Section 11.7 points out that "if the nozzle contour is not proper, shockwaves may occur inside the duct." The chapter then goes on to describe the "method of characteristics" and how this can be used to determine the contour of the nozzle.

According to the MPEP § 2164.01 an analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims so as to enable one skilled in the pertinent art to make and use the claimed invention. The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.

Accordingly, in view of the teachings of Anderson, the Applicants contend that the knowledge of what constitutes a contoured nozzle and how to fabricate such a nozzle was well known in the art and within the grasp of the skilled artisan before the filing date of the instant application. Hence, because the skilled artisan would know what is meant by a contoured nozzle and would know how to fabricate the same, the Applicants contend that claims 12, 31 and 32 are fully enabled in that the skilled artisan could make and use the claimed invention without undue experimentation.

With respect to claim 30, the Office Action asserts that claim 30 recites a "divergent nozzle portion has an inlet cross-sectional area and an exit cross sectional area, said areas being chosen in accordance with the total driver chamber pressure at which said device is arranged to operate so that, in use, the gas flow in said divergent portion is substantially correctly expanded when said particles pass through said divergent portion." The Office Action asserts that there is no description in the specification that would enable a skilled artisan to choose the correct areas in accordance with the total driver chamber pressure. The Office Action acknowledges that the specification states a particular analytical function is employed to ensure correctly expanded flow, however, the Office Action asserts that the analytical function is not disclosed and therefore one of skill would not be able to make or use the Applicants' claimed invention.

The Applicants respectfully disagree and contend that one of skill in the art would readily understand what analytical function to use so as to determine the correct areas of the inlet and exit portions of the nozzle. For instance, in view of the Anderson reference, one of skill in the art would recognize that the particular analytical function to be used is set forth therein as Equation 5.20. To further support this contention the Applicants would like to draw the attention of the Office to Figure 5.9 on page 157 of Anderson. As can be seen with reference to Figure 5.9, the total driver chamber pressure includes the upstream pressure and the down stream pressure (which is atmospheric). This yields a value of P/P_0 as shown in Figure 5.9 (c). As can be seen with reference to Figure 5.9 (b), the Mach number at the exit plane of the nozzle can be calculated (e.g., via Equation 5.20). Figure 5.8 allows one to calculate the appropriate area ratio for the nozzle so as to achieve the Mach number with supersonic flow. Accordingly, the combination of Equation 5.20 with the equation set forth in Figure 5.9 (c) allows one to relate the area ratio to the pressure ratio and thereby determine the correct areas of the inlet and exit portions of the nozzle. Therefore, given any particular driver chamber pressure, the ability of selecting the appropriate cross-sectional area of the inlet and exit of the nozzle portion so as to ensure the gas flow is substantially correctly expanded was well within the skill set of an ordinary practitioner of the art at the time of filing the instant application.

With respect to claim 10, the Office Action asserts that claim 10 recites a quasi-steady flow directed through the divergent nozzle portion is substantially correctly expanded. The Office Action, however, asserts that the specification does not describe how to achieve a correctly expanded flow or how to make a device that can produce such a correctly expanded flow. The Office Action acknowledges that the specification teaches that the nozzle exit area (A_e)/nozzle minimum area (A_1) could range from 1 to 50, however, the Office Action asserts that this ratio is dependent upon the pressure within the nozzle and that the specification has not set forth the specific correlation between the area ratio and nozzle pressure.

For the reasons stated above, the Applicants respectfully disagree and contend that in view of the Applicants' specification and what was generally known at the time of filing the instant application, one of skill in the art would readily know how to correlate the driver pressure with the cross-sectional areas of the nozzle portion so as to achieve a quasi-steady flow that is substantially correctly expanded. As stated above, the Anderson reference clearly teaches the appropriate equations to use and how to use them so as to relate the area ratio to the pressure ratio and thereby determine the correct areas of the inlet and exit portions of the nozzle so as to achieve a substantially correctly expanded flow. Hence, the

Applicants contend that claim 10 is fully enabled in that because the skilled artisan would know how to determine the correct pressure to area ratio, the skilled artisan would be able to make a device that could produce a correctly expanded flow in accordance with the methods of the claimed invention without undue experimentation.

With respect to claim 18, the Office Action asserts that claim 18 recites a reflected expansion wave passing out of the device end terminates the quasi-steady flow. The Office Action asserts that claim 18 is not enabled because the specification does not set forth how long to make the drive chamber so that an expansion wave passing out of the device end terminates the quasi-steady flow.

The Applicants respectfully disagree. Claim 18 merely recites that the quasi-steady flow is terminated when a reflected expansion wave passes out of the downstream end of the device. As shown in Figure 3 of the instant application, the expansion wave 34 initially moves in the upstream direction along the drive chamber and is reflected at the bleed hole, as expansion wave 36, before passing out of the device and thereby terminating the quasi-steady flow. This will happen for all practical lengths of the driver chamber. The duration of the quasi-steady flow can be made shorter by shortening the length of the driver chamber or longer by lengthening the length of the driver chamber. Accordingly, there is a wide range of lengths that can be used and in all practical embodiments the expansion wave will pass out of the device after the particles, regardless of the length. Hence, the choice in length is simply a design feature the appropriate length of which one of skill in the art could readily determine. Therefore, the Applicants contend that claim 18 is fully enabled because the skilled artisan can easily determine the appropriate length of the drive chamber so that a reflected expansion wave passing out of the device end terminates the quasi-steady flow without undue experimentation.

Conclusion as to the rejections under 35 U.C.S.§112, first paragraph

The Applicants submit that the rejection of claims 10, 12, 18, 30, 31 and 32 under 35 U.S.C. §112, first paragraph, have been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

REJECTIONS UNDER §112, ¶2

Claims 24 and 25 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for allegedly omitting essential elements.

The Office Action asserts that claim 24 omits a structure for opening the fluid connection. Accordingly, claims 24 and 25 have been amended thereby rendering this rejection moot. In view of the amendments to claims 24 and 25 the Applicants respectfully request that this rejection be withdrawn.

REJECTIONS UNDER §102

Claims 1-6, 9-12, 14-25, 26, 27, 29-32, 34, 36 and 55 were rejected under 35 U.S.C.§102(b) as allegedly being anticipated by Bellhouse et al. (USPN 5,630,796; "Bellhouse").

The Office Action stated that Bellhouse discloses a needleless injection device that includes a rupturing membrane closure means, substantially constant diameter driver chamber, substantially constant diameter duct section connected to the driver chamber to receive gas therefrom, a dose of particles P upstream of the closure means, divergently contoured nozzle downstream of the duct through which a flow travels, whereby the device generates a shock wave upon rupturing of the membrane.

According to the MPEP, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Additionally, the identical invention must be shown in as complete detail as is contained in the claim. See MPEP 2131.

Elements of the claimed invention include the device being constructed and arranged so that upon opening of the closure means, a primary shock wave is produced and travels along the duct section in a downstream direction and a substantially quasi-steady gas flow is established in the duct section upstream of the primary shock wave. In this manner, a dose of particles is substantially wholly entrained in the substantially quasi-steady flow, accelerated and expelled from the device.

The Office Action acknowledges that establishing a quasi-steady flow upstream of a shock wave as well as entraining and accelerating particles in the quasi-steady flow is not taught by Bellhouse. The Office Action, however, asserts that these elements are inherent to the device set forth in Bellhouse. In support of this assertion, the Office Action states that Bellhouse discloses a similar structure as recited in the Applicants' claims and that due to this similarity the Bellhouse device will inherently function as the device claimed by the Applicants and therefore produce the associated waves and effects in use with shock waves.

The Applicants respectfully disagree.

According to the M.P.E.P. § 2112, in rendering a rejection based on inherency the Office is required to provide evidence that shows inherency. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of the result of

characteristic. In fact, to establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. Inherency may not be established by probabilities or possibilities.

The Applicants contend that the production of a quasi-steady flow upstream of a shockwave that entrains and accelerates substantially all of the dose of particles within the substantially quasi-steady flow is not necessarily inherent within Bellhouse. In support of this contention, the Applicants would like to draw the attention of the Office to column 5, lines 56 to 61 of Bellhouse, wherein it is stated that the particles "travel on or behind the contact surface." Accordingly, because the particles travel on or behind the contact surface the particles are precluded from being entrained within the quasi-steady flow. In fact, Figure 1 of the instant application shows the trajectory of the particles of the Bellhouse device. As can be seen, the particles are entrained in an unclean flow which has shockwaves 16 and expansion waves 15 passing through it. This is different from the flow taught by the Applicants because, as seen with reference to Figure 3 of the instant application, all the particles 33 are passing through an area of flow that has no shockwaves or expansion waves. Therefore, contrary to the assertion of the Office, the production of a quasi-steady flow upstream of a shockwave that entrains and accelerates substantially all of the dose of particles within the substantially quasi-steady flow is not necessarily inherent within Bellhouse. Hence, because these elements are not necessarily present in Bellhouse, the cited reference does not teach every element of the Applicants' claims and therefore does not anticipate the claimed invention.

Conclusion as to the rejections under 35 U.C.S.§102(b)

The Applicants submit that the rejection of claims 1-6, 9-12, 14-25, 26, 27, 29-32, 34, 36 and 55 under 35 U.S.C.§102(a) as allegedly being anticipated by Bellhouse has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

REJECTIONS UNDER §103(A)

Claims 1-7, 9-18, 20-34, 36 and 55 were rejected under 35 U.S.C.§103 (a) as allegedly being unpatentable over Heinzen (WO 97/47730) in view of Bellhouse et al. (USPN 5,899,880; "Bellhouse").

The Office Action stated that Heinzen discloses a needleless injection device that includes a rupturing membrane closure means 18, diameter driver chamber 13, constant diameter duct section 22,

dose of particles in region of closure means 14, divergently contoured nozzle 24 through which a flow travels, whereby the device generates an accelerated gas stream upon rupturing the membrane.

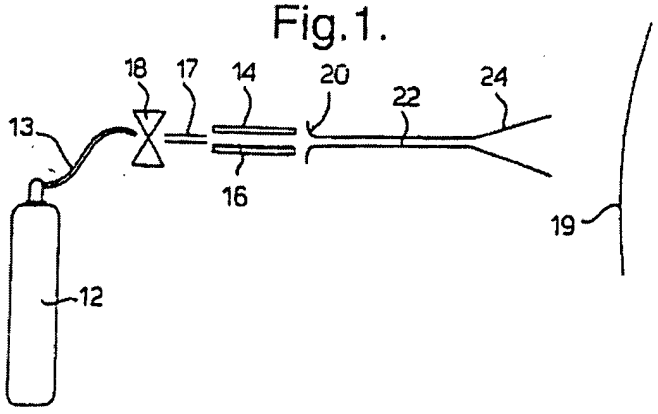
According to the MPEP § 706.02 (j), to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Independent claim 20, the independent claim from which the others depend, is directed to a needleless injection device that includes a driver chamber that is arranged, in use, to contain a charge of pressurized gas, a duct section connected to said driver chamber to receive gas therefrom, a closure means for preventing the flow of gas from said driver chamber to said duct section until said closure means is opened; and a dose of particles positioned within the device in the region of said closure means. The device is constructed such that opening of the closure means produces a primary shock wave which travels along the duct section in a downstream direction so as to establish a substantially quasi-steady gas flow in the duct section upstream of the primary shock wave. In this manner the dose of particles is substantially wholly entrained in the substantially quasi-steady flow, is accelerated thereby and expelled from the device.

The Office Action acknowledges that establishing a quasi-steady flow upstream of a shock wave as well as entraining and accelerating particles in the quasi-steady flow is not taught by Heinzen. The Office Action, however, asserts that these elements are inherent to the device set forth in Heinzen. In support of this assertion, the Office Action states that Heinzen discloses the same structure as recited in the Applicants' claims and that due to this identity the Heinzen device will inherently function as the device claimed by the Applicants and therefore produce the associated waves and effects in use with shock waves.

The Applicants respectfully disagree. The device disclosed in Heinzen is represented in Figure 1 (set forth herein below).

Fig.1.



An embodiment of the Applicants' disclosed device is represented in Figure 5 of the Applicants' application (set forth herein below).

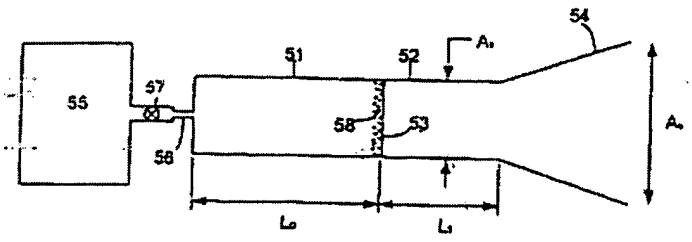


FIG. 5

The Office equates the tubing (13) that connects the compressed gas (12) to the membrane (18) of Figure 1 with the driver chamber (51) of Figure 5. The Office additionally equates the membrane (18) of Figure 1 with the closure means (53) of Figure 5, the acceleration chamber (22) of Figure 1 with the duct section (52) of Figure 5, the carrier particles (16) of Figure 1 with the dose of particles (58) of Figure 5 and the nozzle (24) of Figure 1 with the divergently contoured nozzle (54) of Figure 5.

As set forth above, the device of claim 20 is constructed such that the opening of the closure means (e.g., 53) produces a primary shock wave which travels along the duct section (52) in a downstream direction so as to establish a substantially quasi-steady gas flow in the duct section upstream of the primary shock wave. Hence, the primary shock wave travels in front, or downstream, of the shockwave. This allows the particles to be substantially wholly entrained in a substantially quasi-steady flow.

The Heinzen device, on the other hand, is not configured in this manner. As can be seen with

reference to Figure 1, above, the carrier particles (16) are forward (i.e., downstream) of the tubing element (13; which the Office equates with the Applicants' claimed driver chamber) and membrane (18). Hence, when the membrane (18) is ruptured the particles (16) will be downstream of (e.g., in front of) the primary shock wave. Because the particles will be in front of the primary shock wave the flow produced will be different from that produced by the device claimed by the Applicants. Therefore, Heinzen does not teach or suggest a device that is constructed such that the opening of the closure means (e.g., 53) produces a primary shock wave which travels along the duct section (52) in a downstream direction so as to establish a substantially quasi-steady gas flow in the duct section upstream of the primary shock wave.

Additionally, as can be seen with reference to the above, the device disclosed in Heinzen does not have the same structure as recited in the Applicants' claims and therefore the Heinzen device will not inherently function as the device claimed by the Applicants and will not necessarily produce the same waves and effects. Hence, because these elements are not taught or suggested in Heinzen nor necessarily present therein, the cited reference is deficient in that it does not teach or suggest every element of the Applicants' claims. As Bellhouse '880 was cited for its disclosure of a "replaceable" particle containing capsule that includes particles sandwiched between two membranes and for its disclosure of a high pressure gas it fails to remedy the deficiencies of Heinzen.

In light of the above, the Applicants contend that a *prima facie* case of obviousness has not been established because the combination of Heinzen in view of Bellhouse '880 fails to teach all the elements of the Applicants' claims, namely a device that is constructed such that the opening of the closure means produces a primary shock wave which travels along the duct section in a downstream direction so as to establish a substantially quasi-steady gas flow in the duct section upstream of the primary shock wave.

Claims 19 and 37 were rejected under 35 U.S.C.§103 (a) as allegedly being unpatentable over Heinzen (WO 97/47730) in view of Bellhouse et al. (USPN 5,899,880; "Bellhouse") in further in view of Bellhouse '478.

Both of claims 19 and 37 ultimately depend from claim 20. As set forth above, the device of claim 20 is constructed such that the opening of the closure means (e.g., 53) produces a primary shock wave which travels along the duct section (52) in a downstream direction so as to establish a substantially quasi-steady gas flow in the duct section upstream of the primary shock wave. Hence, the primary shock wave travels in front, or downstream, of the shockwave. This allows the particles to be

substantially wholly entrained in a substantially quasi-steady flow. As set forth above, the combination of Heinzen in view of Bellhouse '880 is deficient in that it fails to teach all the elements of the Applicants' claims, namely a device that is constructed such that the opening of the closure means produces a primary shock wave which travels along the duct section in a downstream direction so as to establish a substantially quasi-steady gas flow in the duct section upstream of the primary shock wave. As Bellhouse '478 was cited for its disclosure of scoring a rupturable membrane and selecting different gases to give different velocities it fails to remedy the deficiencies of Heinzen in combination with Bellhouse '880.

In light of the above, the Applicants contend that a *prima facie* case of obviousness has not been established because the combination of Heinzen in view of Bellhouse '880 and further in view of Bellhouse '478 fails to teach all the elements of the Applicants' claims, namely a device that is constructed such that the opening of the closure means produces a primary shock wave which travels along the duct section in a downstream direction so as to establish a substantially quasi-steady gas flow in the duct section upstream of the primary shock wave.

Conclusion as to the rejections under 35 U.C.S.§103 (b)

The Applicants submit that the rejection of claims 1-7, 9-18, 19, 20-34, 36, 37 and 55 under 35 U.S.C.§103 (b) as allegedly being obvious over Heinzen in view of Bellhouse '880 and further in view of Bellhouse '478 has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number KEMP-002.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: May 30, 2006

By: _____
James S. Nolan
Registration No. 53,393

Enclosure(s): Replacement Drawings, Exhibit A.

BOZICEVIC, FIELD & FRANCIS LLP
1900 University Avenue, Suite 200
East Palo Alto, California 94303
Telephone: (650) 327-3400
Facsimile: (650) 327-3231

F:\DOCUMENT\KEMP\002\Amdt resp OA dated 12-28-05.doc

Appendix

REPLACEMENT DRAWINGS

Submitted with Response to Office Action

dated December 28, 2005